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10/082,221	02/26/2002	Mark W.J. Ferguson	39-257	2577

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NIXON & VANDERHYE P.C.
8th Floor
1100 North Glebe Rd.
Arlington, VA 22201

EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,221	FERGUSON, MARK W.J.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 3/11/04, has been entered into the record.

B. Claims 1-10 were pending in the application. However, these claims were canceled in the Amendment dated 3/11/04 and new claims 11-19 were added. Therefore, claims 11-19 are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

A. The objection to the specification has been withdrawn in view of Applicants' identification of the IL-10 used in the application as that of human.

3. Claim Objections

A. All claim objections have been withdrawn in view of Applicants' cancellation of the originally numbered claims and the submission of new claims 11-19 which remedy these objections.

4. Claim Rejections - 35 USC § 101

A. The rejection of claims 1-10 under 35 USC 101 has been withdrawn in view of Applicants' cancellation of these claims and the submission of new claims 11-19 which do not recite "the use of."

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 11-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of promoting wound healing by using human IL-10, does not reasonably provide enablement for the use of 'partially-modified forms" thereof, or for the use of proteins with at least "60%," "80%," or "95%" homology to human IL-10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

This issue is similar to the one found on pages 3-4 of the Office Action dated 10/6/03 regarding canceled claims 1-10. Therefore, Applicants' arguments will be applied to newly added claims 11-19. Applicants argue that both fragments and partially modified forms of IL-10, and methods by which such

fragments and forms can be produced, were well known to those skilled in the art at the priority date. Applicants have also provided a prior art document to this effect (WO 95/03411). Applicants argue that, in order to be functional, such an agent must merely retain "the anti-inflammatory healing functionality of IL-10." Applicants also argue that they have provided documents discussing suitable models for wound healing.

These arguments have been considered, but are not deemed persuasive. First, Applicants have not identified exactly where in the WO document it discusses modifications of IL-10. The only support for modifications to IL-10 in that document that the Examiner was able to find was on page 5, line 7 to page 6, line 30. However, these modified forms of IL-10 are limited to point mutations as well as truncations of no more than 11 or 12 residues from either the carboxy or amino terminus. This document does not provide sufficient support for the alteration of as many as approximately 62 or so residues (60% homology) of human IL-10. In addition, this document only provides support for point mutations and truncations. The present invention is not limited to these regions. Therefore, these modifications to IL-10 can be made anywhere along the entire protein. The art, as cited by applicants, does not support such alterations. Therefore, even though the claims of the present invention provide functional limitations (retain the anti-inflammatory healing functionality of IL-1 and reduce scarring), Applicants have not provided sufficient guidance or working examples of any protein other than that of full-length human IL-10. Though Applicants have provided evidence that the art recognizes wound healing, this does not remedy the situation. The Examiner further addresses Applicants arguments below -

1. The quantity of experimentation necessary

Applicants argue that WO 95/03411 also discloses methods suitable for the production of further fragments and derivatives capable of use in accordance with the present invention. Again, this does not remedy the deficiency in Applicants' specification of how to make functional IL-10 fragments since the WO document simply discloses how to physically *produce* these fragments and derivatives. There is no discussion that these fragments or derivatives would be functional. Applicants are only pointing to the fact that since the sequence of IL-10 was known, it would be routine to make these fragments. Respectfully, this employs only simple recombinant techniques and does not teach the artisan which fragments are enabled. Again, this WO document only provides support for point mutations and truncations. The present invention is not limited to these regions. Therefore, the quantity of experimentation to make functional fragments is undue.

2. The amount of direction or guidance presented

Applicants argue that the activity required of a fragment or partially modified form of IL-10 suitable for use according to the invention is clearly set out at page 3 of the instant application. This activity, the criterion being that an agent retains the anti-inflammatory healing functionality of IL- 10, is recited in the claims as now presented. Applicants submit that, since it is the presence or absence of this activity that determines whether or not a fragment or partially modified form of IL-10 is suitable for use in the claimed methods, the identification of this activity as a "benchmark" for assessing therapeutic effectiveness provides adequate direction to the skilled person to enable the identification of suitable agents.

These arguments have also been considered, but are not deemed persuasive. While Applicants have provided a functional limitation in the claims, Applicants have not provided sufficient guidance or direction for the artisan to make IL-10 fragments which retain this activity. Again, neither the present specification, nor the prior art teachings enables the artisan to make a functional IL-10 fragment or derivative in which up to 40% of the protein can be altered. Due to this lack of sufficient direction and guidance, the quantity of experimentation to produce variants other than the full-length human IL-10 and those variants taught in WO 95/03411 is undue due.

3. The presence or absence of working examples

Applicants also argue that the instant specification contains a well-worked example of the use of native human lL-10 to promote healing with reduced scarring and that this example thus sets out the activity that must be achieved by an agent in order to be suitable for use according to the invention.

This argument has been considered, but is not deemed persuasive. As stated by Applicants, the specification only provides one working example of an IL-10 molecule which can be reduce scarring – the full-length IL-10 protein. Applicants have not provided sufficient guidance or working examples of any other protein other than that of the full-length IL-10. Fragments and modified forms of IL-10 would contain one or more amino acid substitutions, deletions, insertions and/or additions to IL-10. Applicants have provided no guidance as to what critical residues are required to maintain the functional characteristics of IL-10 in the promotion of would healing or for the treatment of fibrotic disorders.

4. The nature of the invention

Applicants argue that the invention lies in a field of the art in which a certain degree of experimentation (such as pilot studies, clinical trials etc.), is necessary, for example, in order to meet statutory regulations.

This argument has been considered, but is not deemed persuasive. While it is true that a certain degree of experimentation is necessary, the present invention requires undue experimentation. Up to 62 amino acids can be altered in the native IL-10 molecule and Applicants have only shown one working example. The guidance provided in the WO 95/03411 document provides minimal guidance regarding the degree of experimentation necessary to practice the claimed invention. Therefore, undue experimentation would be required to practice the claimed invention.

5. The state of the prior art

Applicants further argue that, at the priority date of the instant application, a number of fragments and partially modified forms of 1L-10, and pharmaceutical compositions comprising same, were known to those skilled in the art. Furthermore, since both the amino acid sequence of IL-10 protein and the DNA sequence of the gene encoding the protein were known to the skilled person, along with a number of suitable techniques for modification of proteins and genes, there existed the potential for further modified forms of IL-10 to be readily generated.

These arguments have been considered, but are not deemed persuasive. Again, as previously stated in this rejection, only a small number of fragments of IL-10 (WO 95/03411) were known at the time of the invention (point mutations and small truncations). However, the scope of the present invention is not limited to these alterations and no guidance is provided on how to make other types of alterations while still retaining the biological activity of native IL-10. Though the state of the art would allow the artisan to physically produce these fragments via recombinant techniques, this does not allow the artisan to identify functional fragments of IL-10. Respectfully, undue experimentation is based on "make and use" not "make and test." Though models of would healing may have been known in the art at the time of the present invention, this does not remedy the fact that undue experimentation would be required to make the variants encompassed by the claimed invention.

6. The relative skill of those in the art

Applicants argue that those involved in research leading to the production of novel clinical therapies are familiar with the need to undertake literature searches to identify up to date information regarding the field in question.

This argument has been considered, but is not deemed persuasive. Literature searches would not reduce the amount of experimentation required to make functional IL-10 fragments. The question is was this invention enabled at the time of filing. Applicants have only provided one WO document discussing a specific set of IL-10 fragments. The present invention allows for up to 62 of 157 amino acids to be altered at any given time. This may include additions, deletions, substitutions or other chemically altered amino acids. Given the sheer number of possible alterations to IL-10, the skill in the art would not be sufficient enough to make and use the present invention without undue experimentation.

7. The predictability or unpredictability of the art

Applicants argue that the prior art available to the skilled person provided both examples of fragments and partially modified forms of IL-10, and also a range of methods by which further fragments and partially modified forms of IL-10 could be produced. Thus the art can be regarded as predictable in terms of the ability to produce suitable candidates for use in accordance with the methods of the invention. Furthermore, the prior art contains many examples of well characterized wound healing models by which the functionality of such candidate agents can predictably be assessed.

These arguments have been considered, but are not deemed persuasive. The breadth of the claims is excessive with regard to Applicants claiming the use of any an all fragments and partially modified forms of IL-10. Fragments and modified forms of IL-10 would contain one or more amino acid substitutions, deletions, insertions and/or additions to IL-10. Applicants have only provided guidance and working examples of the use of IL-10 to promote would healing and have provided no guidance or working examples of fragments or modified forms of IL-10. Applicants have provided no guidance as to what critical residues are required to maintain the functional characteristics of IL-10 in the promotion of would healing or for the treatment of fibrotic disorders. For these reasons, it is not predictable to one of ordinary skill in the art how to make a functional IL-10 other than that of the full-length IL-10 disclosed. As stated previously, undue experimentation is based on "make and use" not "make and test." Though models of would healing may have been known in the art at the time of the present invention, this does not remedy the fact that it would be unpredictable to the artisan how to make functional IL-10 derivatives other than those taught in WO 95/03411.

8. The breadth of the claims

Finally, Applicants argue that, given the ease with which one skilled in the art would be able to identify and produce fragments and partially modified forms of IL-10, and also the ready availability of validated wound healing models by which the suitability of such agents for use in methods of the invention can be ascertained, Applicant submits that the breadth of the presently presented claims is appropriate.

These arguments have also been considered, but are not deemed persuasive. As stated above, fragments and modified forms of IL-10 would contain one or more amino acid substitutions, deletions, insertions and/or additions to IL-10. Applicants have only provided guidance and working examples of the use of IL-10 to promote would healing and have provided no guidance or working examples of fragments or modified forms of IL-10, other than those taught in WO 95/03411. Applicants have provided no guidance as to what critical residues are required to maintain the functional characteristics of IL-10 in the promotion of would healing or for the treatment of fibrotic disorders. Therefore, the breadth of the claims is excessive with regard to Applicants claiming the use of any an all fragments and partially modified forms of IL-10. Again, though models of wound healing may have been known in the art at the time of the present invention, this does not remedy the fact that the breadth of the claims, given the minimal guidance and working examples, is excessive.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming any an all fragments and partially modified forms of IL-10. There is also a lack of guidance and working examples of these molecules as well as which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional IL-10 other than that of the full-length of the disclosed IL-10, or those taught in WO 95/34011, lead the Examiner to hold that undue experimentation is required to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 11-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This issue is similar to the one found on page 4 of the Office Action mailed 10/6/03 for canceled claims 1-10. Therefore, Applicants' arguments will be applied to newly added claims 11-19. Applicants argue that the claims as now presented define suitable fragments of IL-10 for use in the methods of the invention with reference to the biological function that must be achieved by such fragments ("a fragment of human IL-10 which retains the anti-inflammatory healing functionality of IL-10"). Applicants further argue that suitable modified forms, or fragments thereof, for use in the methods of the invention are now defined in terms of both their biological function and their homology with human IL-10, (i.e. "a partially modified form of human IL-10, or a fragment thereof, which has at least 60% homology with IL-10 and retains the anti-inflammatory healing functionality of IL-10") and these homologous fragments can be readily determined using widely available commercial software packages.

These arguments have been considered, but are not deemed persuasive. Again, these are genus claims. Fragments and modified forms of IL-10 would contain one or more amino acid substitutions, deletions, insertions and/or additions to IL-10. In fact, IL-10 fragments which are 60% identical to IL-10 would have 62 residues altered out of a total of 157. Applicants have only provided adequate written description of the full-length human IL-10 as well as a small number of point mutants and truncated IL-10 molecules (WO 95/03411). The specification and claims do not provide an adequate description as to what changes could be made to the full-length IL-10 molecule in order to retain its desired function. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Therefore, one of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Simply stating that the fragments must retains the anti-inflammatory healing functionality of IL-10 is, respectfully, insufficient to demonstrate that Applicant was in possession of the claimed genus at the time the invention was made. Even if software packages were able to identify the degree of *homology* to human IL-10, this does not remedy the fact that the specification and claims do not provide an adequate description as to what

changes could be made to the full-length IL-10 molecule in order to retain its desired *function*. It is believed that all pertinent arguments have been addressed.

7. Claim Rejections - 35 USC § 112, first paragraph – new matter

A. Claims 11-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 recites "anti-inflammatory healing functionality." No support for this phrase could be found in the specification. The closest term which could be found was in relation to "inhibiting inflammation at a wound site or site of a fibrotic disorder" (page 3, second paragraph of the specification). It appears that the phrase "anti-inflammatory healing functionality" broadens the scope of the claims in light of what is taught in the specification as originally filed. Applicants are required to point out exactly where in the specification this term is defined. Claims 12-19 are rejected since they depend from rejected claim 11. **This is a new matter rejection**.

8. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1-4 under 35 USC 112, second paragraph, regarding the fact that the claims do not set forth any steps involved in the method/process, has been withdrawn in view of the cancellation of these claims and the fact that the new claims do not raise this issue.

B. The rejection of claims 1-3, 7 and 9 under 35 USC 112, second paragraph, regarding the fact that it is not clear whether the IL-10 is used to promote reduced scarring, or if IL-10 is to be used to treat fibrotic disorders which have reduced scarring as compared to other fibrotic disorders has been withdrawn since, though the claims may be broad, they are not indefinite. Though these original claims have been cancelled, none of the newly submitted claims raise this issue.

C. The rejection of claim 5 under 35 USC 112, second paragraph, regarding the fact that it recites "a method. . .comprising the use" has been withdrawn in view of the cancellation of this claim and the fact that the new claims do not raise this issue.

D The rejection of claims 1-5 under 35 USC 112, second paragraph, regarding the fact that they are incomplete for omitting essential steps, such omission amounting to a gap between the steps has been withdrawn in view of the cancellation of these claims and the fact that the new claims do not raise this issue.

E. Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the phrase "anti-inflammatory healing functionality" are undefined. The closest term which could be found was in relation to "inhibiting inflammation at a wound site or site of a fibrotic disorder" (page 3, second paragraph of the specification).

9. Double Patenting

A. Claims 11-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,387,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent recite methods for promoting wound healing with reduced scarring, as well as treating fibrotic disorders, by administering IL-10 to a person in need of such treatment. Applicants did not provide any arguments, but noted that this rejection can be overcome by the filing of a Terminal Disclaimer. Therefore, Applicants urged the Examiner to hold the rejection in abeyance until the case is otherwise in condition for allowance.

10. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al (WO 93/19770 – on the IDS dated 10/6/03). This rejection was inadvertently made under 35 USC 102(a). However, the basis for the rejection remains the same regardless and, in view of Applicants' arguments, would have been maintained regardless of falling under 35 USC 102(a) or (b). This rejection was initially

made for claims 1-3, 5, 6, 9 and 10. These claims have been cancelled. However, the rejection is being made/maintained for new claims 11-19 and Applicants' arguments will be considered here.

Applicants argue that Gordon teach the healing of acute and chronic inflammation and not the healing of a wound or fibrotic disorder and that there is no indication in Gordon et al. that IL-10 can be used to reduce scarring. These arguments have been considered, but are not deemed persuasive. It would be expected that wounds, even if not all, would lead to inflammation and, conversely, that inflammation may be caused by a wound. A good example is a compound fracture. In this situation, a bone has broken and has torn through the skin. Therefore, with this wound, one would expect there to be inflammation. In addition, one would expect the healing of the torn skin to involve scar tissue. Since Gordon covers any population which has either acute or chronic inflammation, then the artisan, following the teaching of Gordon, would administer IL-10 in order to reduce inflammation. Since IL-10 has the inherent property of reducing scarring, the artisan, in practicing the method of Gordon, would, inherently, be practicing the method of the claimed invention. The process steps of administering IL-10 are the same regardless of whether the purpose is to reduce inflammation or reduce scarring (Ex parte Novitski, 26 USPQ 1391). Gordon also teach pharmaceutically acceptable carriers (at least page 18, lines 28-32), in conjunction with an agent which promotes the healing of wounds (IL-4; Abstract; page 10, lines 21-28; page 18, lines 28-32), including chronic wounds (at least the Abstract), wherein the agent is administered to the site of the wound (Abstract). Applicants do not specifically teach administering IL-10 at a concentration of 1 μM – 10 μM or 2.5 μM – 5 μM. However, again, for the purposes of this rejection, "inflammation," as disclosed by Gordon, is being considered a "wound," or, more specifically, that a wound would lead to inflammation, or that inflammation may be caused by a wound. Therefore, the concentrations of IL-10 used in the method of Ferguson to treat inflammation (i.e. wound) would inherently be the same concentration of IL-10 required to heal wounds with reduced scarring, in absence of evidence to the contrary.

B. The rejection of claims 1-3, 5, 6, 9 and 10 under 35 USC 102(a) in view of Ferguson et al. (WO 93/19769 – on the IDS dated 10/6/03) has been withdrawn in view of Applicants' cancellation of these claims and the submission of new claims 11-19 which add percent identity limitations. Furthermore, Applicants' argument that Ferguson et al. do not disclose the use of IL-10 or a fragment thereof, and do not disclose the use of a partially modified form of IL-10 having at least 60% homology with human IL-10 is persuasive.

C. The rejection of claims 1-3, 5, 6, 9 and 10 under 35 USC 102(a) in view of Schwartz et al. (WO 92/11861 – on the IDS dated 10/6/03) has been withdrawn in view of Applicants' cancellation of these claims and the submission of new claims 11-19 which add percent identity limitations. Furthermore, Applicants' argument that Schwartz et al. do not disclose the use of IL-10 or a fragment thereof, and do not disclose the use of a partially modified form of IL-10 having at least 60% homology with human IL-10 is persuasive.

D. The rejection of claims 1-3, 5, 6 9 and 10 under 35 USC 102(a) in view of Ferguson et al. (U.S. Patent No. 5,972,335) has been withdrawn in view of the fact that the priority date of the present application precedes that of the cited patent.

E. The rejection of claims 1-3, 5, 6 9 and 10 under 35 USC 102(e) in view of Strom et al. (U.S. Patent No. 6,403,077) has been withdrawn in view of the fact that these claims have been canceled and new claims 11-19 recite that the patient is in need of treatment of a wound or fibrotic disorder with reduced scarring. This rejection was inadvertently made under 35 USC 102(b) in the Office Action mailed 10/6/03. Ferguson teach a method of increasing the half-life of IL-10 by fusing it to an enzymatically inactive protein for the purpose of preventing or treating numerous disorders, including diabetes and cancer, none of which involved wound healing or fibrotic disorders, or would be expected to require reduced scarring, nor could the Examiner make a *prima facie* case that the method of Ferguson anticipated the present invention. Therefore, the Examiner could not conclude that an artisan practicing the method of Ferguson would inherently be practicing the method of the present invention.

11. Claim Rejections - 35 USC § 103

A. The rejection of claims 4 and 10 under 35 USC 103(a) in view of either Ferguson et al. (WO 93/19769 – on the IDS dated 10/6/03) or Schwartz et al. (WO 92/11861 – on the IDS dated 10/6/03) has been withdrawn in view of Applicants' cancellation of these claims and the submission of new claims 11-19 which add percent identity limitations. Furthermore, as argued by Applicants, neither reference suggests that IL-10, its fragments, or partially modified forms thereof, had utility in promoting healing with reduced scarring.

B. The rejection of claims 4 and 10 under 35 USC 103(a) in view of Gordon et al. (WO 93/19770 – on the IDS dated 10/6/03) has been withdrawn in view of the fact that upon further review of the cited reference, Gordon et al. do teach treatment of chronic wounds (i.e. inflammation). This is discussed in detail in the above rejection of all claims under 35 USC 102(b) over Gordon. Therefore, these claims fall in the realm of inherent as opposed to obviousness.

C. The rejection of claims 7 and 8 under 35 USC 103(a) in view of either Ferguson et al. (WO 93/19769 – on the IDS dated 10/6/03) or Schwartz et al. (WO 92/11861 – on the IDS dated 10/6/03) has been withdrawn in view of Applicants' cancellation of these claims and the submission of new claims 11-19 which add percent identity limitations. Furthermore, as argued by Applicants, neither reference suggests that IL-10, its fragments, or partially modified forms thereof, had utility in promoting healing with reduced scarring.

D. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (WO 93/19770). This rejection was initially made for claims 7 and 8. These claims have been cancelled. However, the rejection is being maintained for new claims 16 and 17 and Applicants' arguments will be considered here.

Applicants argue that none of these documents would have suggested that IL-10, its fragments, or partially modified forms thereof had utility in promoting healing with reduced scarring. This argument has been considered, but is not deemed persuasive. As described in detail in the above rejection over Gordon et al. of claims 11-19 under 35 USC 102(b), it would be expected that wounds, even if not all, would lead to inflammation, or that inflammation may be caused by a wound. Applicants do not specifically teach administering IL-10 at a concentration of 1 μM – 10 μM or 2.5 μM – 5 μM. However, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have performed routine experiments in order to determine the dosage required to practice the present invention. It would be expected that drug concentrations in the μM range would be included in these routine experiments.

12. Conclusion

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
June 01, 2004

ROBERT LANDSMAN
PATENT EXAMINER